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# FDA Scrutinizes Birth Control Drugs

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WASHINGTON -- The government is considering setting higher standards for birth control drugs used by millions, saying that newer pills appear to be less effective at preventing pregnancy than those approved decades ago.

The Food and Drug Administration will ask a panel of experts Tuesday and Wednesday whether it should require new contraceptive drugs to meet a standard of effectiveness before they are approved for the market.

More than 60 percent of U.S. women between the ages of 15 and 44 use some sort of contraception, with 11.6 million choosing birth control pills, according to a 2005 survey by the Guttmacher Institute, a nonprofit research group. The global market for hormonal contraceptives was $5 billion in 2005, according to an estimate by U.K. research firm Piribo.

In briefing documents posted to its Web site, the FDA says newer contraceptives have been less effective _ at times, with twice the failure rate _ than previous products, most likely because manufacturers have started using lower doses of hormones that stop ovulation.

"The very first pills were very high dose and carried risks of blood clots and cardiovascular problems that would be unacceptable to most women," said Amy Allina, program director of the National

Women's Health Network. "Today most birth control pills are very safe for the vast majority of women."

The FDA will ask its experts whether the benefit of that improved safety profile outweighs a slightly increased risk of unwanted pregnancies.

The original birth control pills approved in the 1960s allowed less than one pregnancy when taken by 100 women for at least a year, the FDA said. But in the last decade, the government has approved pills allowing more than two pregnancies for every 100 woman-years of use.

The FDA will ask the 14 members of its reproductive drugs panel whether that difference in performance is large enough for concern. The panel is chiefly made up of gynecologists and obstetricians, but it also includes a statistician and a neurologist.

Government scientists are in disagreement over whether there should be a strict limit on the failure rate a drug can have and still be approved. And they are looking at requiring manufacturers to include a more representative mix of women in the clinical trials for their new products.

Companies often exclude women who smoke, are overweight or have a history of heart problems from their trials. The FDA says this makes it difficult for scientists to judge the safety and efficacy of the drugs in the real world.

Heather Boonstra, a policy analyst for Guttmacher Institute, said the FDA is likely holding its meeting now to stay abreast of a number of innovative contraceptive products that are now in development.

One such product is Wyeth Pharmaceuticals' Lybrel, which is designed to be the first birth control pill for continuous use, 365

days a year. The drug is pending approval in the U.S. and in Europe. A Wyeth representative said the company would attend the meeting but did not plan to make a presentation.

Other recent innovative products have proved problematic for the agency. In September, for example, the FDA warned women that Johnson & Johnson's birth control patch Ortho Evra could raise their chances of developing blood clots in the legs and lungs. Johnson & Johnson markets a number of traditional contraceptives, including its top-selling birth control pill, Ortho Tri-Cyclen.

The FDA also weathered heavy criticism over its handling of Barr Pharmaceutical Inc.'s controversial "morning after pill," Plan B, which was only approved for over-the counter sales after two years of wrangling between politicians and consumer advocates.

Barr also markets the more traditional pill Seasonale.